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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,263

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,263	Applicant(s) OMURA ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 3-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/17/05, 5/11/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The application should be reviewed for errors. Error occurs, for example, in the spelling of "avermectin" in claim 1.

In keeping with scientific custom, the names of microorganisms should be italicized or underlined.

For the sake of consistency, claims 1 and 2 should be amended to read "glycosylated".

The amendment filed 4/27/09 is acknowledged.

Claims 1-2 are being considered on the merits. Claims 3-15 are withdrawn from consideration as directed to a non-elected invention.

Claim 1 is being examined ONLY to the extent that it pertains to a *Streptomyces cyaneogriseus* subspecies *noncyanogenus* that has **the ability to produce C-13 glycosylated nemadectin.**

The rejections under 35 U.S.C 101 and deposit are withdrawn in view of applicant's amendments and averments, respectively.

Specification

The amendment filed 4/27/09 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

At page 5, the addition of the phrase "comprising gene groups of avermectin aglycon biosynthesis of *Streptomyces avermitilis*". This phrase was now added by amendment without an indication of the source therefor in the as-filed specification. This does not appear to be a translation error as alleged.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the as-filed specification for "comprising gene groups of avermectin aglycon biosynthesis of *Streptomyces avermitilis*". This phrase was now added by amendment without an indication of the source therefor in the as-filed specification. The "gene groups" intended are not identified in this record with any particularity.

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the recitation of "comprising gene groups of avermectin aglycon biosynthesis of *Streptomyces avermitilis*", even when reading the claim in light of the specification. The "gene groups" intended are not identified in this record with any particularity. See also the new matter rejection *supra*.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carter *et al.*, (J. Antibiot. 1988, Vol. 41, No. 4, p. 519-529) taken with MacNeil *et al.* (U.S. Patent No. 5,312,753) and Huang *et al.* (PGPUB 2005/0003409) .

The claim is directed to a strain of *Streptomyces cyaneogriseus* subsp, *noncyanogenus* that has the ability to produce C-13 glycosylated nemadectin.

Carter *et al.* teaches a strain of *Streptomyces cyaneogriseus* subsp, *noncyanogenus* that produces of nemadectin (See, e.g., page 519). MacNeil *et al.* teaches a related strain of *Streptomyces* that has the ability to produce a closely related 13-glycosylated product. Thus, one of ordinary skill in the art would have reasonably expected the strain of Carter *et al.* to produce 13-glycosylated nemadectin at least to some extent under appropriate culturing conditions, particularly in the absence of evidence to the contrary.

In addition, one of ordinary skill in the art would have been motivated to make a strain of *Streptomyces cyaneogriseus* subsp, *noncyanogenus* having the required glycosylation ability in view of the disclosure of Huang *et al.* relating to the cloning of the entire metabolic pathway of nemadectin and related products.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the strain of *Streptomyces cyaneogriseus* subsp, *noncyanogenus* if necessary, by using the disclosure of Huang *et al.* as guidance to produce a strain capable of the required glycosylation for the expected benefit of having greater versatility in the production of pharmaceutically useful medicaments.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

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Applicant's arguments directed to stereoselective biosynthesis are not material to the invention as claimed. The claim 1 merely requires the microorganism to be capable of producing C-13 "glycosidated" nemadectin. There is no indication as to the specific strain of *Streptomyces cyaneogriseus* subsp, *noncyanogenus* intended, the "gene groups" to be provided or its specific properties. The claims strain is only required to be capable of producing C-13 "glycosidated" nemadectin to some extent. Even though there is not specific disclosure therefore, it is apparent that the strain of Carter has the ability of producing C-13 glycosylated nemadectin at least to some extent, and Applicant has not shown otherwise.

In addition, one of ordinary skill in the art would have been motivated to make a strain of *Streptomyces cyaneogriseus* subsp, *noncyanogenus* having the required glycosylation ability in view of the disclosure of Huang *et al.* relating to the cloning of the entire metabolic pathway of nemadectin and related products.

Applicant has disclosed one specific strain that meets the asserted requirements, i.e., the strain designated FERM BP-8394, the subject of claim 2. With all due respect it is noted that claim 2 is not included in the rejection (Response, page 15, paragraph 2).

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Claim 2 would be allowable upon the removal of the phrase "comprising gene groups of avermectin aglycon biosynthesis of *Streptomyces avermitilis*", from the specification at page 5..

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
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